

## Medication Guide

### **SolagJ Topical Solution**

(mequinol 2%, tretinoin 0.01%)

#### **INFORMATION FOR PATIENTS**

**Please read this Medication Guide carefully before you start to use your medicine. If you have any questions, or are not sure about any of the information on SolagJ, ask your doctor.**

The active ingredients in SolagJ (pronounced so-la-JAY) are mequinol and tretinoin.

SolagJ also contains ethyl alcohol (77.8% v/v), polyethylene glycol 400, butylated hydroxytoluene, ascorbic acid, citric acid, ascorbyl palmitate, edetate disodium, and purified water .

#### **What is the Most Important Information about SolagJ?**

SolagJ is a prescription medication. It should only be used under supervision of your doctor as part of a sun avoidance program. This program should also include avoiding exposure to artificial sunlight (sunlamps) and avoidance of direct sunlight by wearing protective clothing.

SolagJ does not permanently “cure” solar lentigines, also known as brown “age” or “liver” spots. In clinical trials, most patients experienced some degree of darkening of their spots over time.

Follow the instructions for application of SolagJ carefully. Avoid getting the medication on your normal-toned skin, in your eyes, nose, or mouth.

SolagJ can cause the side effect, halo hypopigmentation, which is lightening of the skin surrounding the spot being treated, within the 6 month treatment period.

**Warning: SolagJ should not be used if you are pregnant, attempting to become pregnant, or at a high risk of pregnancy. Consult your doctor for adequate birth control measures if you are a female of child-bearing potential. Avoid sunlight and any other medicines that may increase your sensitivity to sunlight (see below).**

There is very limited information on the safety of SolagJ in people with moderately or darkly pigmented skin.

#### **What Can I Expect From SolagJ?**

SolagJ is a prescription medication used for the topical treatment of solar lentigines, also known as brown Age@ or Aliver@ spots.

Studies show that after 24 weeks, for lesions of the face, 57% of patients using SolagJ had moderate improvement or greater, with 3% experiencing complete clearing of all treated lesions. Another 28% of patients had slight improvement and 15% had no change or worse (less than 1% of patients had worsening of their lesions). After 24 weeks for lesions of the forearms/back of hands, 54% of patients using SolagJ experienced moderate improvement or greater, with 1% experiencing complete clearing of all treated lesions. Another 26% had slight improvement and 20% had no change or worse (less than 1% of patients had worsening of their lesions). Approximately 9% of patients who had success in the treatment of their age spots also experienced the side effect, halo hypopigmentation, which is lightening of skin surrounding the treated spot. Evidence has not been established concerning the effectiveness of SolagJ in the treatment of other hyperpigmented conditions of the skin.

Improvement in the color of the treated age spots occurs gradually. Do not be discouraged if you see no immediate improvement. Be patient. If SolagJ is going to have a beneficial effect for you, it may take up to six months of treatment before full beneficial effects are seen. After stopping treatment with SolagJ, the age spots may darken again over time.

The effectiveness of SolagJ in treating solar lentigines, also known as brown “age” or “liver” spots, beyond 6 months has not been established.

### **Who should not use SolagJ?**

SolagJ should not be used if you are pregnant, attempting to become pregnant, or at a high risk of pregnancy. Consult your doctor for adequate birth control measures if you are a female of child-bearing potential.

It is not known if SolagJ is passed to infants through breast milk. Do not use SolagJ if you intend to breast feed, unless advised otherwise by your doctor.

SolagJ should not be used on children.

Do not use SolagJ if you are allergic to any ingredients in this medicine. If you are allergic to any of the ingredients, tell your doctor.

If you are sunburned, do not use SolagJ until you have fully recovered.

Do not use SolagJ if you have a skin condition called eczema or other inflamed or irritated chronic skin conditions.

Do not use SolagJ if you are inherently sensitive to sunlight or taking other drugs that increase your sensitivity to sunlight. You should tell your physician if you are also using other medicines that increase sensitivity to sunlight. These medications include but are not limited to: thiazides (used to treat high blood pressure), tetracyclines, fluroquinolones or sulfonamides (used to treat infection), and phenothiazines (used to treat serious emotional problems). If you are taking any prescription medicines, non-prescription medicines or using any facial or skin creams, check with your physician to make sure they do not interact with SolagJ.

There is very limited information on the safety of SolagJ in people with moderately or darkly pigmented skin. If you, or a family member, have a history of vitiligo (a skin condition consisting of white patches on various parts of the body), consult your doctor before using SolagJ.

## **How should I use SolagJ?**

SolagJ is to be used twice daily, at least eight hours apart, or as directed by your doctor. It is a drug for topical use only and is not a cosmetic preparation. Do not use SolagJ around your eyes, lips, creases of the nose or mucous membranes. SolagJ may cause severe redness, itching, burning, stinging, and peeling if applied to these areas. If the product gets in your eyes, rinse thoroughly with water and contact your doctor.

Apply SolagJ to the age spots using the applicator provided with the medication. Avoid application of SolagJ to the surrounding, normally colored skin. Only enough SolagJ should be applied to make the lesion appear moist - running or dripping of the medication should be avoided. Applications of larger amounts of SolagJ, or more frequent applications than recommended, will not lead to more rapid or better results, and marked redness, peeling, irritation or hypopigmentation may occur. You should not shower or bathe the treatment areas for at least 6 hours after application of SolagJ.

Stop treating any age spots that become the same color or lighter than your normally colored skin. If the skin surrounding an age spot becomes lighter than your normally colored skin, stop treating that age spot and contact your doctor regarding continued use of SolagJ to that age spot.

If you forget or miss a dose of SolagJ, do not try to make it up. Return to your normal application schedule as soon as you can.

If sensitivity or increased irritation occurs, stop use of SolagJ and contact your doctor.

If the age spots become darker with treatment, stop use of SolagJ and contact your doctor.

Do not use SolagJ for any condition other than for which it was prescribed by your doctor. Do not give it to other persons or allow other persons to use it.

You may use cosmetics after applying SolagJ but you should wait 30 minutes before applying.

## **What should I avoid while using SolagJ?**

SolagJ increases your sensitivity to sunlight. Sun exposure (natural or artificial) to areas of the skin treated with SolagJ should be avoided. Wear protective clothing if exposure to the sun cannot be avoided. Patients using SolagJ should practice a comprehensive sun protection program. Following discontinuation of SolagJ, patients should continue to practice a comprehensive sun protection program.

SolagJ should be used with caution if you are also using other topical products with a strong drying effect on the skin, products with high concentrations of alcohol, astringents, spices or lime, medicated soaps or shampoos, permanent wave solutions, electrolysis, hair removal products or waxes, or other preparations or processes that may dry or irritate your skin. If you are using any of these types of products, tell your doctor before using SolagJ.

### **What are the possible or reasonably likely side effects of SolagJ?**

SolagJ may cause redness, stinging, burning or irritation on areas of the skin where it is applied. It may also cause peeling and itching of the areas where applied.

Excessive or prolonged application of SolagJ may cause the treated age spots or surrounding skin to become temporarily lighter than your normally colored skin. Discontinue application of SolagJ to any such affected areas.

### **How can I get additional information?**

This leaflet summarizes the most important information about SolagJ. If you would like more information, talk to your doctor.

### **How should SolagJ be stored?**

SolagJ should be protected from light by returning the bottle to the carton after each use. Store at room temperature, 15-30°C (59-86°F).

SolagJ is FLAMMABLE. Keep away from heat or open flame.

Keep this and all medication out of the reach of children.

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